

Serial No. 10/009,972

Reply to Office Action of December 19, 2003



Attorney Docket No. UAB-16102/22

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard J. Whitley et al.

Serial No.: 10/009,972

Group Art Unit: 1632

Filing Date: February 14, 2002

Examiner: Scott David Priebe

For: HERPES SIMPLEX VIRUS EXPRESSING FOREIGN GENES
AND METHOD FOR TREATING CANCERS THEREWITH

**DECLARATION OF RICHARD J. WHITLEY,
JAMES M. MARKERT, GEORGE Y. GILLESPIE
AND JACQUELINE N. PARKER UNDER 37 CFR §1.131**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We, Richard J. Whitley, James M. Markert, George Y. Gillespie and Jacqueline N. Parker, declare as follows:

1. We are co-inventors of the invention disclosed in the above-identified application for patent.
2. We have reviewed and are familiar with the U.S. Patent Application No. 2002/0098170 listing Wechsler et al. as inventors.
3. We understand that claims 1, 2, 5, 9 and 13-15 of the application have been rejected under 35 U.S.C. §102(e) as being anticipated by Wechsler et al. It is our understanding that Wechsler et al. is cited for teaching a pharmaceutical composition comprising substantially aneurovirulent replication-competent HSV-1 whose genome comprises deletion of both copies of

the γ 34.5 gene and LAT coding sequence and a nucleic acid sequence encoding IL-12 or GM-CSF operably linked to a LAT promoter. We understand that Wechsler et al. is also cited as teaching a method for treating cancer in a subject by administering a therapeutically effective amount of the HSV directly to the tumor by injection.

4. We understand that Wechsler et al. filed their U.S. Patent Application 2002/0098170 on November 29, 2001 and, further, that U.S. Patent Application 2002/0098170 was filed claiming priority as a divisional application to Application No. 09/299,817 filed April 26, 1999.

5. We state that a composition of the present invention including a replication competent herpes simplex virus vector comprising a nucleic acid sequence encoding interleukin-12, granulocyte macrophage colony stimulating factor or cytosine deaminase, operatively linked to a promoter was in fact invented by us before April 26, 1999.

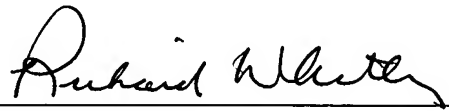
6. We state that a method for treating a subject suffering from cancer, including the step of administering to a subject a therapeutically effective amount of a replication competent herpes simplex virus comprising a nucleic acid sequence encoding interleukin-12, granulocyte macrophage colony stimulating factor, or cytosine deaminase, such that an anti-cancer response is induced in the subject, was in fact invented by us before April 26, 1999.

7. We submit that notarized copies of lab notebook pages and a summary sheet describing the contents of some of the lab notebook pages have previously been placed on record as evidence that inventions described in our application were in fact invented before April 26, 1999.


8. We declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and that these

statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therein.

Date: 2/13/04


Richard J. Whitley

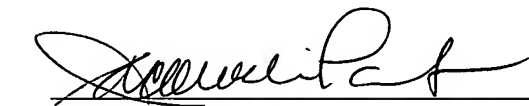
Date: 2/13/04


James M. Markert

Date: 2/13/04


George Y. Gillespie

Date: 2/13/04


Jacqueline N. Parker